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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/857,305 | 10/03/2001 | Robert C. Brunham | 1038-1153MIS | 3368 |

24223 7590 05/27/2005

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| EXAMINER | |
|---|---|
| MINNIFIELD, NITA M | |
| ART UNIT | PAPER NUMBER |
| 1645 | |

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/857,305 | BRUNHAM ET AL. | |
| | Examiner | Art Unit | |
| | N. M. Minnifield | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19,21,22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

***Response to Amendment***

1. Applicants' amendment filed June 3, 2004 is acknowledged and has been entered. Claims 1-18, 20, 23 and 29-40 have been canceled. Claims 19, 21, 22 and 24-26 have been amended. Claims 19, 22 and 24-28 are now pending in the present application. Claim 21 is withdrawn. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below. This Office Action contains new grounds of rejection, however they were necessitated by Applicants' amendment to the claims. This is a Final Office Action.

2. This application contains claim 21, drawn to an invention nonelected with traverse in the paper filed October 6, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Claims 19, 22 and 24-28 are objected to because of the following informalities: claim 19, line 5, "promote"; should this be "promoter". Appropriate correction is required.

4. The disclosure is objected to because of the following informalities: The specification refers to US Patent Applications that are now issued patents; see for example p. 4, l 26 and 31, p. 9, l. 5. Appropriate correction is required.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 recites the limitation "promoter" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 19, 22 and 24-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 20, 22 and 24-28 of copending Application No. 10/699683. Although

the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an attenuated strain of a bacterium harbouring a vector (plasmid vector or pcDNA3/MOMP) comprising a nucleic acid molecule encoding a *Chlamydia* protein (i.e. major outer membrane protein (MOMP) of a strain of *Chlamydia* (or *C. trachomatis*) and a promoter sequence (cytomegalovirus promoter) operatively coupled to said nucleic acid molecule for expression of said protein in cells of a host to which the attenuated strain is administered but not in the attenuated bacteria (*Salmonella typhinmurium*).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 19, 22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gurtiss III (5389368) taken with Brunham (WO 98/02546).

The claims are directed to an attenuated strain of a bacterium harbouring a vector (plasmid vector or pcDNA3/MOMP) comprising a nucleic acid molecule encoding a major outer membrane protein (MOMP) of a strain of *Chlamydia* (or *C. trachomatis*) and a promoter sequence (cytomegalovirus promoter) operatively coupled to said nucleic acid molecule for expression of said protein in cells of a host to which the attenuated strain is administered but not in the attenuated bacteria (*Salmonella typhinmurium*).

Gurtiss III teaches an attenuated *Salmonella typhimurium* bacteria that is harboring a vector comprising heterologous nucleic acid molecule that encodes for a second pathogenic microorganism for example *C. trachomatis* (col. 6). Gurtiss teaches that the vaccine can be effective against bacterial disease agents such as *Chlamydia trachomatis* that causes venereal diseases and eye infections (col. 6). Incorporation of the recombinant nucleic acid molecule into the attenuated bacteria (*Salmonella typhimurium*) is accomplished through the use of plasmid, phage or cosmid vectors (col. 11; col. 6; claims). "The recombinant DNA is packaged within a phage such as transducing phage or cosmid vectors. Once the recombinant DNA is in the carrier cell, it may continue to exist as a separate piece (generally true of complete transmitted plasmids) or it may insert into the host cell chromosome and be reproduced with the chromosome during cell division." (col. 11) Gurtiss teaches the claimed invention except for the specific a nucleic acid molecule encoding a MOMP from *C. trachomatis,* that the promoter is a cytomegalovirus promoter and the plasmid vector pcDNA3/MOMP.

However, Brunham teaches DNA immunization against Chlamydia infection comprising nucleic acid, including DNA, immunization to generate a protective immune response in a host, to a major membrane protein of a strain of Chl*a*mydia (*C. trachomatis*), preferably contains a nucleotide sequence encoding a MOMP that generates antibodies that react with MOMP and a promoter sequence operatively couples to the first nucleotide sequence for expression of the MOMP in the host (abstract; p. 3; pp. 20-21 Example 4). The non-replicating vector may be formulated with a pharmaceutically acceptable carrier for in vivo administration to the host (abstract; p. 3). Brunham teaches that the promoter may be the cytomegalovirus promoter and that the non-replicating vector may be plasmid

pcDNA3 into which the nucleotide sequence is inserted (i.e. pcDNA3/MOMP) (pp. 4-5; p. 8). The plasmid vector containing the MOMP gene from *Chlamydia trachomatis* was pcDNA3 with transcription under control of the human cytomegalovirus promoter (pp. 16-17; p. 25, Table 2; claims). The prior teaches the use of the promoters and vectors for expression of the Chlamydia MOMP for protecting a host against Chlamydia infection.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the attenuated *Salmonella typhimurium* bacteria of Gurtiss to include harboring a nucleic acid molecule encoding a Chlamydial protective MOMP of Brunham because Gurtiss teaches that through administration of a live attenuated bacteria that encodes a protective protein a host is stimulated to produce an immune response directed against the expressed gene product and with a subsequent administration of purified protein, an enhanced secretory immune response is obtained. The person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining an attenuated *Salmonella typhimurium* bacteria that comprises the nucleic acid, plasmid and promoter of Brunham that encodes a protective MOMP of *Chlamydia trachomatis*, because Gurtiss teaches that Chlamydia is a pathogen that causes venereal diseases and eye infections. The attenuated bacteria is capable of expressing a recombinant gene product, wherein use of a nucleic acid molecule that encodes a protective MOMP results in stimulating an immune response against the *Chlamydia trachomatis* MOMP. The claimed invention is prima facie obvious in view of the teachings of Gurtiss taken with Brunham, in the absence of unexpected results or other convincing evidence to the contrary.

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
May 17, 2005